

### **REMARKS/ARGUMENTS**

In response to the Final Office Action mailed January 23, 2006, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this Amendment, Claim 1 is proposed to be amended, no claims are added, and no claims are cancelled without prejudice so that Claims 1-7 are pending in the application. No new matter has been introduced.

Claims 1-6 were rejected as being unpatentable over U.S. Patent No. 5,876,367 to Kaganov et al. (Kaganov) in view of U.S. Patent No. 6,726,701 to Gilson et al. (Gilson) and Claims 1-7 were rejected as being unpatentable over Kaganov in view of Gilson and further in view of U.S. Patent No. 5,423,849 to Engelson et al. (Engelson). These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria."

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d1596 (Fed. Cir. 1988).”

The present invention, as claimed in amended Claim 1, is directed to a cardiopulmonary bypass filter system that comprises a filter membrane having openings. The openings have variable diameters with respect to one another and the diameter of the openings range from about 20 to 300 microns. In addition, additional distinct fibers are attached to the circumference of the openings of the filter membrane to increase embolic capture.

None of the references, whether taken alone or in combination, discloses or even remotely suggests these extra fibers on a filter membrane. The threads disclosed in Kaganov are the threads that make up the filter and not cilia type extra threads extending in from the circumference of the holes. The threads of Engelson may be any type of thread but are not extending from the openings of a filter membrane. It is clear from the specification that the fibers of Claim 1 are additional fibers since in some exemplary embodiments the openings are formed by drilling through a specific material and thus have no fibers. In addition, these fibers are only attached to the circumference of existing openings and were never intended to be part of the mesh. Since not all of the features are suggested by the references, a *prima facie* case of

obviousness has not been made. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

In addition, assuming for the sake of argument that the references did suggest the claimed elements, there is simply no motivation to combine the references.

The U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") restated the legal test applicable to rejections under 35 U.S.C. 103 (a) (*In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir., July 15, 1998)). The Court stated:

[V]irtually all [inventions] are combinations of old elements. Therefore an Examiner may often find every element of a claimed invention in the prior art. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the Examiner to show a motivation to combine the references that create the case of obviousness. The Board [of Appeals] did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the field of the art. If such a rote indication could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct the suggestion to combine requirements stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness. *In re Rouffet*, 47 USPQ2d 1457-58 (Fed. Cir., July 15, 1998) (citations omitted, emphasis added).

More recently, the Federal Circuit again dealt with what is required to show a motivation to combine references under 35 U.S.C. 103 (a). In this case the court reversed the decisions of the Board of appeals stating:

[R]ather than pointing to specific information in Holiday or Shapiro that suggest the combination..., the Board instead described in detail the similarities between the Holiday and Shapiro references and the claimed invention, noting that one reference or the other-in combination with each other... described all of the limitations of the pending claims. Nowhere does the Board particularly identify any suggestion, teaching, or motivation to combine the ... references, nor does the Board make specific-or even inferential-findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any factual findings that might serve to support a proper obviousness analysis.

In re Dembiczak, 50 USPQ2d 1614, 1618 (Fed. Cir., April 28, 1999) (citations omitted, emphasis added).

Thus, from both in re Rouffet and in re Dembiczak it is clear that the Federal Circuit requires a specific identification of a suggestion, motivation, or teaching why one of ordinary skill in the art would have been motivated to select the references and combine them or an identification of the level of skill in the art at the time of the invention which would make him likely to combine his skill with the teachings of the art to come up with the invention. This the Examiner has not done. There is simply no reason to combine the references. Two of the references disclose filter devices while the third, Engelson, discloses a vasoocclusive device. The purpose of this device is to occlude and not filter. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

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A favorable Action on the merits is earnestly solicited.

Respectfully submitted,

/Carl J. Evens/

By: \_\_\_\_\_

Carl J. Evens

Reg. No. 33,874

Attorney for Applicants

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2518  
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